IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:

09/865.822

Filed:

05/25/2001

Examiner:

Zec, Flip

Art Unit:

Confirmation No.: 5846 3744

Applicants:

John E. Davis, et al.

Title:

FLUID ABSORBENT ARTICLE FOR SURGICAL USE

Attv. Doc.:

TRIL-05

Cincinnati, Ohio

45202

MAIL STOP Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL DECLARATION OF JOHN E. DAVIS

John E. Davis, being first duly cautioned and sworn, states as follows:

- 1. My name is John E. Davis. I am one of the inventors in U.S. Patent No. 6,603,052.
- 2. On June 29, 2010, I originally filed a Petition to Accept an Unavoidably Delayed Payment of the Maintenance Fee for U.S. Patent No. 6,603,052. That Petition was dismissed.
- 3. The Decision indicated that I have the burden of establishing that I exercised the due care of a reasonably prudent person. I assert that I did act reasonably prudent in handling my affairs associated with the patent, to the extent that I could even understand or remember what was occurring at the time the patent issued, and when I received the original patent and a letter regarding the payment of maintenance fees by particular deadlines.

- 4. It was necessary that I turn my business affairs, including the `052 maintenance tracking issue, over to my daughter because of my condition and the fact that I could not reliably handle my business and financial matters at the time of the stroke in 2003, as set forth in my original Declaration.
- 5. Because of my lack of memory with respect to any exposure to the original patent, the receipt of that original patent, and any accompanying letter, I did not even have the opportunity to know about the maintenance fee issue or the maintenance fee due dates for the patent. I did not know of, or did not remember, the original patent or maintenance fee issue to even know I had to set up a reminder, or that I had to pay maintenance fees. As such, as I stated in my original Declaration, I could not reasonably set up a docketing system, as I was mentally incapable of even knowing I had to do so. That lack of knowledge was the result of the stroke and my lack of knowledge regarding the maintenance fee continued from that time frame in 2003, up through the 2007 expiration of the patent, and also up until I inadvertently discovered the patent in the archived files. I did not even have the knowledge of the issue to take any such steps. (Original Davis Declaration Paragraph 23.)
- 6. However, from further discussing this issue with my daughter, I have come to discover that, on my behalf, around the time of receiving the original `052 Patent in 2003, she had indeed initially set up an internal docketing and reminder system to address the issue of the maintenance fees for the `052 Patent.

- 7. Given my mental and physical state at that time, it was certainly reasonable and prudent for me to rely upon my daughter. That reliance was well-placed as she handled various of my business and financial matters in 2003, and put in a calendar date for the time frame of August, 2006 to remind her, and in turn, remind me, regarding the maintenance fees and the need to pay them. This was my most reasonable chance at addressing the issue.
- 8. My physical and mental ailments in the time frame of August, 2003 were real and significant. Attached hereto as Exhibit A are documents from my neurology doctor, Marvin H. Rorick, M.D. regarding the details of my stroke in May of 2003. Also attached as Exhibit B are documents from Santosh G. Menon, M.D. and supporting documents setting forth my reduced cardiac function. The effects of these ailments still affect me today (Original Davis Declaration Paragraph).
- 9. From the time of the expiration of the patent up until the time that I discovered the original patent on September 22, 2009, I did not even know that any action had to be taken with respect to paying the maintenance fees. Once I discovered that fact, as I noted in my original Declaration (Declaration of John E. Davis Paragraph 5), I made diligent efforts in the arduous task to gather the information necessary to establish that this delay in payment of the maintenance fee was truly unavoidable.

- 10. My personal health issues were not immaterial to the delay in paying the maintenance fee. Because of the stroke, I was mentally incapable of even knowing about the maintenance fee issue. Thus, this prevented me from even taking steps, on my own, with respect to scheduling a reminder to pay the fee. The lack of that initial knowledge with respect to the maintenance fee issues did not change over the course of the time from the issuance of the original patent, up to the date that the first maintenance fee was due, and then up to the date that I discovered the original patent in the archived files. I am not asserting that I was not mentally or physically capable of setting up some kind of further reminder system during that time, but I did not even have the knowledge to know that maintenance fee payments were due.
- that reliance was both reasonable and prudent, as Ms. Brumbaugh helped me to take care of various personal and business matters. However, her reminder system that she put into place on my behalf to provide a reminder with respect to the maintenance fee issue also failed. Therefore, I did not have any personal knowledge that I was supposed to pay the maintenance fee, and because of the mechanical failure of my daughter's reminder system, my daughter, Ms. Brumbaugh, also did not have knowledge that maintenance fees were due that she could pass on to me. As such, it was unavoidable that we failed to have the requisite knowledge to take any further steps for payment of the maintenance fee.

- 12. In addressing the assignment issue noted in the Decision, I have also managed, through significant effort, to find and contact Mr. Klonne, the other inventor, to confirm that assignment. He is filing a Declaration herewith indicating that he had assigned his entire ownership interest in the `052 Patent to me. Therefore, I am the sole owner of the `052 Patent.
- 13. I was not aware of the need to pay patent maintenance fees due to my stroke. I could not act on information of which I was not aware. Nor could I know to make even a further reminder system that might supplement the system that failed. I made the prudent decision of turning over my matters, including the patent matter, to my daughter, Ms. Brumbaugh. My daughter did set up a docketing/reminder system for the patent on my behalf, and so I had a system in place, although through my daughter. That system failed unfortunately. Because I had no original knowledge of the issuance of the patent or the maintenance fee issue and my docketing system in place at the time associated with my daughter failed, I had no way to know that the original maintenance fee due dates had come and passed. From the time the patent was granted, up through the time of discovery of the original patent, it was unavoidable that I would not know to take further action with respect to maintenance fee payment or to set up another reminder system of my own. When I found out about the maintenance fee issue, I took the necessary steps to pay it and explain the unavoidable nature of the situation. Accordingly, it was unavoidable that the maintenance fee was delayed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the issued Patent referenced.

Further Declarant sayeth naught.

	fordam
11/18/10	
Date	John E. Davis

Document #1285937



From the desk of.

Marvin H. Rorick, M.D.

11/8/10

To whomit may concern,
The enchosed documentation
indicates my theatment

To whomit may concern,
the enchosed documentation

Please all of any questions. MHKanak MD

513-241-2370

ENCOUNTER REPORT
DAVIS, JOHN E (M) 54 Years 03/06/1949 UN:343527C-4
ACCT # 341387

PRINTED:11/8/10 DOS:05/23/2003 OFFICE CHART 10

RORICK, MARVIN H, MD

OUTPATIENT VISIT : WELLINGTON

05/23/2003 OFFICE CONSULT COMP HIGH COMPLEX 99245

DIAGNOSES/PROBLEMS

MAJOR

BRAIN INFARCTION UNSPECIFIED

The patient is a 54 year old right handed man who reports the first stroke which occurred in 1998. This apparently involved the right temporal region of the brain and was not associated with lasting neurologic deficits. He was doing well until 5/6/03 when he felt mildly confused and had some dizzy fogginess. He was able to drive to work and the following day was noted to be somewhat forgetful. Another CT scan of the brain was performed and revealed a new area of infarction in the right occipital pole. Echocardiographic study was performed and revealed an apical thrombus and he was started on Coumadin anticoagulation. Carotid ultrasound studies have been performed and have revealed no abnormalities. He has been doing moderately well and has been able to return to work. He does not report a severe visual impairment.

MINOR

SLEEP APNEA HYPERCHOLESTEROLEMIA

HEALTH REVIEW ------

SOCIAL HISTORY

Married, currently working sales.

ALCOHOL USE

0

PERSONAL SMOKING HISTORY

Λ

PULSE 72

BLOOD PRESSURE 110/80

HEIGHT

6'2"

ACTUAL WEIGHT LB 223

HEART

Regular rate and rhythm. No murmur appreciated.

MENTAL CTATIC

He reports some cognitive difficulty with poor memory on occasion.

CRANIAL NERVE EXAMINATION

Extraocular movements conjugate and full. Visual fields no deficit identified on the left. No visual neglect. He is able to read.

PRINTED:11/8/2010

DOS:05/23/2003

ENCOUNTER REPORT

DAVIS, JOHN E (M) 54 Years 03/06/1949 UN:343527C-4

--PHYSICAL EXAM--

MUSCLE STRENGTH

Symmetric in arms and legs.

SENSORY EXAM

Intact to all modalities.

GAIT

Stable.

ALLERGIES

NO KNOWN DRUG ALLERGIES

----- MEDICATION -----

CLOPIDOGREL (PLAVIX) 75 MG QD
PRAVASTATIN (PRAVACHOL) 20 MG QD
WARFARIN (COUMADIN) 7.5 MG 3 DAYS A WEEK 5 MG 4 DAYS A WEEK

------ THERAPIES ------

PLAN OF ACTION

His echocardiogram reveals presence of a likely apical thrombus which was not identified in the work up performed in 1998. He has been anticoagulated with Coumadin. It is recommended that he have a transesophageal echocardiogram performed in approximately six months.

----- ADMINISTRATIVE DATA

REVIEWED AND SIGNED BY RORICK, MARVIN H, MD
TRANSCRIPTION DATE
5/30/2003
TRANSCRIPTIONIST
RT
COPY

JEFFREY MERLING, M.D. ENCOUNTER REVIEW DATE 6/2/03

*** END OF REPORT ***

The Ohio Heart & Vascular Center

John F. Schneider, MD, FACC President & Chief Executive Officer

Charles W. Abbottsmith, MD, FACC Geoffrey A. Answini, MD, FACS Scott A. Behrens, MD, FACC Thomas M. Broderick, MD, FACC Pete L. Caples, MD, FACC Joseph K. Choo, MD, FACC Eugene S. Chung, MD, FACC Gregory B. Clarke, MD, FACC J.D. Corl, MD, FACC, FSCAL Peter J. Engel, MD, FACC JoAnna L. English, MD, FACC Joel B. Forman, MD, FACC George S. George, MD, FACC A. Daniel Glassman, MD, FACC Madhukar Gupta, MD Monica G. Hunter, MD, FACC Tom D. Ivey, MD, FACS, FACC Dean J. Kereiakes, MD, FACC James A. Kong, MD, FACC George T. Manitsas, MD, FACC Wojciech Mazur, MD, FACC Santosh G. Menon, MD, FACC Donald L. Mitts, MD. FACS Thomas I. Murtaugh, MD, FACC Thomas M. O'Brien, MD Gregory A. Parker, MD, FACC Robert A. Pelberg, MD, FACC Joel P. Reginelli, MD, FACC John Paul Runyon, MD, FACC lan J. Sarembock, MD, FACC Edward J. Schloss, MD, FACC John F. Schneider, MD, FACC Patrick J. Shea, MD, FACC Jason A. Smith, MD, FACC Terri L. Stewart-Dehner, MD, FACC John J. Szawaluk, MD, FACC Christopher J. Thoresen, MD, FACC Theodore J. Waller, MD, FACC

Joe Barone, CNP Kathleen Daly, CNP Jaime Ginney, PA Cheryl Hickey, CNP Amy Rich, CNP Ann E. Suttmann, CNP

Offices in the Communities of:

Anderson Batavia Batesville

Batesville Hamilton

Harrison

Hillsboro Kenwood

Lawrenceburg

Lawrencebur Mason

Middletown

Mt. Airy

Mt. Auburn Montgomery

Oaklev

West Union

Western Hills

Wilmington

John Davis 223 Congress Street New Richmond, OH 45157 513-379-6464

To Whom It May Concern:

Mr. Davis has been a patient of mine since July of 2002. He has unfortunately had various ailments, but I have been specifically treating him with his diagnosis of Wolff-Parkinson-White syndrome (WPW) and heart failure (HF). WPW essentially causes a heart arrhythmia that can be life-threatening if untreated. The arrhythmias associated with WPW can, at the very least, cause structural changes to the heart leading to HF. There is no definitive cause for Mr. Davis's HF, but it is often thought that undetected, untreated and more specifically for Mr. Davis, uncontrolled arrhythmias can cause HF. Mr. Davis started the appropriate medications and has had several interventions in an attempt to correct the arrhythmias associated with WPW. Mr. Davis seemed to have a particularly difficult time with arrhythmias between February 2, 2007 and June 29, 2010.

11/5/10

Generally, HF leads to reduced cardiac function; leading to reduced blood flow to all body organs and the brain. Symptoms of HF include shortness of breath especially upon exertion, fatigue, reduced mental capacity, swelling, reduced appetite. HF is a progressive disease that can eventually cause damage to other organs including but not limited to the kidneys, liver and brain. Our goal is to slow the progression of HF with medications, procedures, devices as well as diet.

Please feel free to contact my office, with Mr. Davis's written permission, for any further information regarding Mr. Davis.

Sincerely,

Santosh G. Menon, MD

The Ohio/Heart and Vascular Center/The Christ Hospital

2123 Auburn Ave Suite 137

Cincinnati OH 45219

513-206-1180

DOCTOR DATA

#129082 John Davis (03/06/1949) 61/M

Primary Cardiologist: Santosh G Menon MD PCP: Jeffrey W Merling

PHARMACY

Costco Pharmacy - Mason Medco (Mail Order)

SOCIAL HISTORY

INSURANCE

Medical Mutual of Ohio Health

VITALS

PRIMARY CARE DOCTOR: Jeffrey W Merling

CARDIAC HISTORY

CAD:

1 Cath [Normal coronaries] - 7/3/2002

2 Cath [EF.20, Lateral / Inferior / Apical Dysk, Normal Coronaries, Right Dominant] - 8/6/2009

CHF/CM:

ldiopathic Cardiomyopathy [EF.53 by 2D/CFD Echo, Mild Septal Hypo, Mild MR, Mild LVH] - 11/7/2006

Idiopathic Cardiomyopathy [EF.33 by 2D/CFD, Apical Hypo, Mild LVH, dilated LA] - 8/8/2008

3 RHC [RA Mean 4, PA Systolic 24, PA Diastolic 13, PA Mean 18, PWP 6, CO 3.1, CI 1.4, SVR 21.8, PVR 3.8] - 8/6/2009

Date: 10/25/2010 9:07 AM

Arrhythmia:

WPW, paroxysmal tachycardia [RFA, Left posteroseptal AP; inducible AVNRT: RFA of AV node slow pathway] - 4/22/1997

2 Nonsustained VT

3 Syncope [Head- up Tilt Table Study: Vasodepressor response 115/84 >> 77/50 mmHg; 54 >> 56 bpm] -

7/15/2002

4 DCCV - 3/22/2007

5 A Fib [ER at TCH, started on pacerone] - 5/7/2007

AFlutter [EPS, RA 3-D map: focal AT with early activation in right posterosuperior RA septum; RFA no effect on tachycardia. LA 3-D map: Complex left atrial flutter with multiple loop (figure of eight) reentry, LA roof to posterior wall, and CW around RPV, CCW around LPV] - 7/9/2007

7 A Flutter [Successful PVI with demonstration of exit block. Unsuccessful ablation for A Flutter] - 12/7/2007

8 PAF [DCCV, Betapace 80 mg q12h and Coreg 12.5 mg bid] - 1/2/2008

9 Syncope [Neurally-mediated mechanism suspected.] - 10/4/2008

NICM EF 33%, CHF III, PAF and Aflutter s/p RFA, recurrent near syncope, Hx CVA [ICD, AV Medtronic D154AWG Virtuoso] - 10/20/2008

PVD:

1 Hemispheric CVA - 20002 Hemispheric CVA - 5/2003

Risk Factors:

4 Dyslipidemia

5 Family History of CAD [Less than 60 years of age]

CARDIAC PROCEDURES:

Invasive:

Cath (EF.20, Lateral / Inferior / Apical Dysk, Normal Coronaries, Right Dominant) - 8/6/2009

Cath (Normal Coronaries) - 7/3/2002

RHC (Cath lab: RA Mean 4, PA Systolic 24, PA Diastolic 13, PA Mean 18, PWP 6, CO 3.1, CI 1.4, SVR 21.8, PVR 3.8) - 8/6/2009

DOCTOR DATA

Date: 10/25/2010 9:07 AM

#129082 John Davis (03/06/1949) 61/M

Primary Cardiologist: Santosh G Menon MD

PCP: Jeffrey W Merling

Echo/MUGA:

2D/CFD (EF.23, Moderate LAE, Moderate TR, LAE, Mild PR, Severe MR, poor coaptation of MV leaflets, vena cava dilation, RVSP 53 mmHg) - 8/4/2009

2D/CFD (EF.33, Apical Hypo, Mild LVH, dilated LA) - 8/8/2008

2D/CFD (EF.33, Distal-Anterior / Distal-Inferior / Apical Akin, Moderate TR (Pk 48), Impaired Relaxation Diastolic Dysfunction, Severe MR) - 8/31/2010

2D/CFD (EF.33, Moderate-Severe Apical Hypo, Mild LVH, Mild MR, moderately dilated LA) - 4/28/2008

2D/CFD (EF.53, Mild Septal Hypo, Mild MR, Mild LVH) - 11/7/2006

DCCV (Initial Rhythm A Flutter, Final Rhythm A Flutter, Max Joules 200, 2 Shocks) - 5/2/2007

DCCV (Initial Rhythm A Flutter, Final Rhythm Sinus, Max Joules 200, 1 Shock) - 1/2/2008

Devices (Dual Chamber (Medtronic-D154AWG), Virtuoso DR; RA 5076-52 LCe/RAA; RV 6947-65 LCe/RVA) - 10/20/2008

EKG (Atrial Flutter 2:1) - 12/20/2007

EKG (Atrial Flutter 2:1, RATE 78 QRS 178 QT 500) - 11/30/2007

EKG (Atrial Flutter 3:1, HR 93) - 2/18/2008

EKG (PSVT, Rate 152) - 5/2/2007

EKG (PVCs, Sinus Rhythm, First Degree AVB, rate 71 QRS 98 QT/QTc 430/468) - 7/17/2008

EKG (Rare PACs, Sinus Rhythm, First Degree AVB, Rate 66 QRS 84 Qt 429) - 5/3/2007

EKG (Sinus Rhythm, First Degree AVB, borderline low voltage in frontal leads, borderline R wave progression, QRSD 0.081) - 2/5/2008

EKG (Sinus Rhythm, First Degree AVB, QRSD 0.086) - 2/21/2006

EKG (Sinus Rhythm, First Degree AVB, rate 66 bpm, PR 253, QRS 92, QTc 472) - 4/7/2008

EKG (Sinus Rhythm, First Degree AVB, rate 72 qrs 102 qt 443) - 1/7/2008

EPS (recurrent AF due to LA flutter Multiple loop reentry) - 7/9/2007

Holter (non-sustained VT) - 6/11/2002

RFA (Indication WPW, Ablation of left posteroseptal accessory pathway at Allegheny Univ.) - 4/22/1997

Tilt Table (Positive tilt table test with a vasodepressor response) - 7/15/2002

Stress Tests:

MPI (EF.35, Abnormal, evidence of prior MI in the LAD region, no evidence for stress induced ischemia) - 8/11/2006

CXR (, Stable mild cardiomegaly. No acute cardio-pulm process.) - 8/23/2010 Sleep Study (OSAS: Mild. Treatment: CPAP, AHI 12.1) - 7/10/2002

DIAGNOSIS HISTORY

Old or Healed CVA Ventricular Tachycardia Idiopathic Cardiomyopathy Atrial Flutter

Old or Healed CVA on plavix, cardiac source Paroxysmal Atrial Fibrillation

Other Primary Cardiomyopathy

Shortness of Breath

Arteriovenous Fistula

AV ICD in Situ

Mitral Regurgitation

Status Post Radiofrequency Ablation

Pre-Excitation/WPW

CRT/AICD/PCD in Situ

Palpitations

DOCTOR DATA Date: 10/25/2010 9:07 AM

#129082 John Davis (03/06/1949) 61/M

Primary Cardiologist: Santosh G Menon MD PCP: Jeffrey W Merling

Sleep Apnea s/p ablation

Chronic Systolic Heart Failure

MEDICATIONS

Brand Generic Dose Betapace Sotalol Hcl 120mg Twice a day Carvedilol Carvedilol 12.5mg Once a day Children"s Aspirin Aspirin 81mg Once a day Co Q-10 Ubidecarenone 10mg Once a day Coreg Carvedilol Once a day 6.25mg Coumadin Warfarin Sodium 5mg As Directed

Coumadin Warfarin Sodium 2.5mg Once a day MG follows

Furosemide Once a day Furosemide 20mg Kondremul Mineral Oil/carrageenan 2.5ml/5ml Once a day Lasix Furosemide 20mg Once in the morning Lovastatin Lovastatin 20mg Once in the evening Mevacor Lovastatin Once in the evening 20mg Multivitamin Multivitamins Twice a day

Plavix Clopidogrel Bisulfate 75mg Once a day

Prednisone Prednisone 10mg Once a day as directed and taper off

Triamterene-hctz

Vitamin C

Vitamin D

Triamterene/hydrochlorothiazid

Ascorbic Acid

Cholecalciferol

Triamterene/hydrochlorothiazid

37.5-25mg Once a day

500mg Twice a day

2000 UnitOnce a day

ALLERGIES

None

LIPID SUMMARY

Date <u>Chol</u> **HDL LDL** Ratio SGPT <u>Trig</u> Non HDL **SGOT** Cpk 01/16/2007 135.00 52.00 69.00 72.00 2.60 83.00 20.00 19.00

FY

STICKY NOTE

no pseudophed

?getting a ablation with waller in july

Consider for HeartNet/PEERLESS-HF trial / cherylbartone

Following the office visit, the patient had a thoracic impedence measurment that was normal. Will therefore not change the diuretics, will have a chest xray and empiric antibiotics, and early follow up with his PCP. Okay to take his steroids for poison ivy. Discussed with Dr. Merling.

JAK 8/23/10